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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/206,132 12/07/98 FREEMAN

G RPI-008CPDV

000959
LAHIVE & COCKFIELD
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BOSTON MA 02109

HM12/1117

EXAMINER

NGUYEN, G

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

11/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/206,132

Applicant(s)

FREEMAN ET AL

Examiner

Quang Nguyen, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 42-43 and 46-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
 - 1. ☐ received.
 - 2. ☐ received in Application No. (Series Code / Serial Number) ____.
 - 3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 42, 43, 46-60, 65-70, 73-75, and 77-87, drawn to an *ex vivo* method of treating or inducing an anti-tumor response in a subject with a tumor using genetically modified tumor cells and a method of modifying a tumor cell *in vitro* or *ex vivo*, classified in class 424, subclass 93.21.
- II. Claims 61-63, 71-74 and 76-87, drawn to a method for treating a subject with a tumor by modifying tumor cells *in vivo* and a method of modifying a tumor cell *in vivo*, classified in class 514, subclass 44.
- III. Claim 64, drawn to a method for treating a subject with a tumor comprising administering T lymphocytes that have been cultured *in vitro* with the tumor cells from the subject and with a stimulatory form of B7-2, to the subject, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Group I (*ex vivo* treatment method) and Group II (*in vivo* treatment method) are directed to methods that

are distinct both physically and functionally, and they require different processing steps, technical considerations and are not required one for the other.

Group I and Group III are drawn to methods that require different processing steps and technical considerations and are not required one for the other. For this instance, the *ex vivo* method of treating or inducing an anti-tumor response in a subject with a tumor of Group I requires the use of genetically modified tumor cells, whereas the treatment method of Group III requires *in vitro* stimulatory T lymphocytes.

Group II and Group III are drawn to methods that require different processing steps and technical considerations and are not required one for the other. The treatment method of Group II requires genetically modification of tumor cells *in vivo*, whereas the treatment method of Group III requires *in vitro* stimulatory T lymphocytes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney Megan E. Williams on October 31, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Deborah Crouch, Ph.D., may be reached at (703) 308-1126, or SPE, Karen Hauda, at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-4242.

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1600/1632